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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,033	02/04/2004	Hartmut Loebermann	785-011686-US (C01)	3888

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EXAMINER	
MORRIS, PATRICIA L	

ART UNIT	PAPER NUMBER
1625	

MAIL DATE	DELIVERY MODE
09/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/772,033	LOEBERMANN ET AL.	
	Examiner	Art Unit	
	Patricia L. Morris	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *5-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 14-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-4 and 14-16 are under consideration in this application.

Claims 5-13 remain held withdrawn from consideration as being drawn to nonelected subject matter 37 CFR 1.142(b).

The restriction requirement is deemed sound and proper and is hereby made FINAL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 14-16 are rejected under 35 U.S.C. 102(a) and/or (b) as being anticipated by Hashimoto et al. and Kotar-Jordan et al. for the reasons set forth in the previous Office action.

Again, Hashimoto et al. and Kotar-Jordan et al. specifically disclose the instant compounds. Note RN 103577-40-8 of Hasimoto et al. or page 289 of Kotar et al. Hence, the instant compound is deemed anticipated therefrom.

Applicants assert that the compounds are distinct from the prior art compounds. The mere insistence by attorney that the claimed compounds are different does not offer any factual evidence to such allegation.

Again, the Declaration of Lobermann, while interesting, if of little if any probative value, because it fails to present any single X-ray crystal diffraction of the instant compounds *vis-à-vis*

the prior art compounds at the same radiation parameters. Note figure 4.21 on page 118 of Bernstein wherein the same compound shows two different X-ray patterns. Further, Davidovich et al. on page 16, states that changes in powder X-ray powder often resulted from experimental artifacts rather than polymorphism and that most of these changes were due to particle size/morphology, sample holder/preparation, and instrument geometry. Mere argument by attorney that changes in X-ray diffraction patterns from experminental artifacts are not relevant does not obviate the rejection.

Contra to applicants' assertions in the instant response, even small differences in X-ray diffraction pattern is not singly providing support for new crystalline hydrates. X-ray diffraction pattern **alone** does not demarcate the identity of two products. It is well recognized in the crystalline solid art that sometimes the difference in X-ray diffraction pattern is very minor and must be carefully evaluated before a definitive conclusion is reached. See US Pharmacopia of record. Page 272 of Bernstein of record shows that two identical X-ray patterns, but one is the chemical compound pigment Yellow 14, wherein R is CH_3, while the other is the pigment Yellow 63, R is Cl. Thus, this is an example of identical X-ray displayed by different compounds. The figure on page 273 (newly cited to show additional facts) shows two X-ray diffraction patterns collected on crystals and crystals after melting. Although, there are new peaks, the authors concluded that "it may not be a pure modification:, *i.e.,* not a true polymorph.

Claim Rejections - 35 USC ∋ 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of in view of Hashimoto et al. and Kotar-Jordan et al. in view of Brittain et al., Muzaffar et al, US Pharmacopia, and Concise Encyclopedia Chemistry for the reasons set forth in the previous Office action.

Again, Hashimoto et al. and Kotar-Jordan et al. teach the crystalline forms of the claimed compounds. Note, for example, page 289 of Kotar-Jordan et al. Brittain et al. and Muzaffar et al. teach that compounds can exist in different crystalline forms. Note, for example, page 60 of Muzaffar et al. US Pharmacopia and Concise Encyclopedia teach that at any particular temperature and pressure, only one crystalline form is thermodynamically stable. Hence the claimed crystalline form as well as its relative selectivity of properties *vis-a-vis* the known compound are suggested by the references. It would appear obvious to one skilled in the art in view of the references that the instant compound would exist in different crystalline forms.

The declaration of Loberman fails to show any unobvious properties for the instant compounds *vis-s-vis* the prior art compounds. Note Brittain et al. on page 185, where it is stated:

"In 1990 Bryn and Pfeiffer found more than 350 patents on crystal forms granted on the basis of an advantage in terms of stability, formulation, solubility, bioavailability, ease of purification, etc.,". The declaration fails to show any advantage for the instant compounds..

As clearly stated by Brittain (p. 1-2) supra, as well as set forth by the court in In re Cofer (CCPA 1966) 354 F2d 664, 148 USPQ 268, ex parte Hartop 139 USPQ 525, that a product which is merely a different form of a known compound, notwithstanding that some desirable results are obtained therefrom, is unpatentable. The instant claims are drawn to the ***same pure substance*** as the prior art that only have *different arrangements and/or different conformations of the molecule*. A mere difference in a physical property is a well known conventional variation for the same pure substance is *prima facie* obvious.

Mere allegations by applicants in the instant response does not take the place **any objective evidence for the claimed hydrates *vis-à-vis* the prior art hydrates.**

Conclusion

Claims 1-4 and 14-16 are not allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

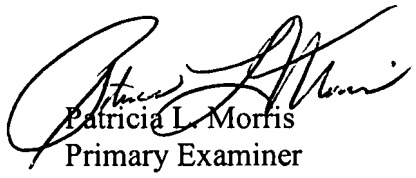
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia L. Morris whose telephone number is (571) 272-0688. The examiner can normally be reached on Mondays through Fridays.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Patricia L. Morris
Primary Examiner
Art Unit 1625

plm
September 10, 2007